Election of Group I (claims 1-11)

Applicant affirms the election of Group I (claims 1-11) made on June 12, 2000.

Rejection under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1-11 under 35 U.S.C. §112, first paragraph, stating that the specification, while being enabling for an immunogenic polypeptide comprising a non-self IgE CH2 domain, a self IgE CH3 domain, and a nonself IgE CH4 domain, does not reasonably provide enablement for: (a) an immunogenic polypeptide comprising a self IgE portion and a non-self IgE portion (claim 1); (b) the immunogenic polypeptide of claim 1, wherein the non-self portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion (claim 5); (c) the immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH2 domain (claim 6), and (d) the immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH4 domain (claim 7). In addition, the Examiner stated that the specification "is insufficient to enable one skilled in the art to practice the invention as broadly claimed in claims 1, 5, 6 and 7 without undue amount of experimentation." Further, the Examiner concluded that an immunogenic peptide for the generation of antibodies to block the binding of IgE with its high-affinity receptor must minimally include a 76 amino acid region between the CH2 and CH3 domains, absent evidence to the contrary, since previous studies teach that this 76 amino acid region must be blocked to inhibit the interaction of IgE with its high-affinity receptor.

Applicant respectfully disagrees and submits that the specification as filed fully enables the originally filed claims. To further prosecution, however, claim 1 has been amended to include the limitations recited in original claim 3. Specifically, claim 1 has been amended to indicate that the self IgE portion contains at least a portion of a CH3 domain of IgE. A person having ordinary skill in the art at the time Applicant's specification was filed would have been able to make and use immunogenic polypeptides as presently claimed once provided with the teachings disclosed throughout Applicants' specification. For example, a person having ordinary skill in the art at the time Applicant's specification was filed would have been able to follow the teachings described in Examples 1 and 2 to make polypeptides containing self and non-self IgE

portions such that the self IgE portion contained at least a portion of a CH3 domain of IgE, without undue experimentation. Likewise, a person having ordinary skill in the art at the time Applicant's specification was filed would have been able to follow the teachings described in Examples 4 and 5 to test polypeptides for the ability to induce an anti-self IgE response, without undue experimentation.

With respect to the Examiner's statement that an immunogenic peptide must minimally include a 76 amino acid region between the CH2 and CH3 domains to generate antibodies to block the binding of IgE with its high-affinity receptor, Applicant respectfully notes that Applicant's specification from page 17, line 29 through page 18, line 1 states that "the binding site for human IgE to the high affinity IgE receptor on mast cells and basophils is not located at the junction between the CH2 and CH3 domains of IgE as previously suggested, but instead is located in the N-terminal region of the CH3 domain." Thus, a person having ordinary skill in the art at the time Applicant's specification was filed given Applicant's specification would have appreciated that the 76 amino acid region located between the CH2 and CH3 domains is not an absolute requirement as suggested by the Examiner.

In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1-11 under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1-11 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner stated that the term "portion" in claims 1, 3, 5, 8, and 10 renders the claims indefinite because the limitation is unclear and ambiguous.

Applicant respectfully disagrees. The term "portion" has a clear and unambiguous meaning. As defined in The American Heritage Dictionary of the English Language (Third Edition, 1992), the term "portion" means "[a] section or quantity within a larger thing; a part of a whole." In light of the clear and unambiguous meaning of the term "portion," Applicant respectfully requests withdrawal of the rejection of claims 1-11 under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 1-4 and 11 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,254,671 (the '671 patent). Specifically, the Examiner stated that the '671 patent "teaches an immunogenic polypeptide comprising self and non-self portions of human IgE, including a human CH3 domain."

Applicant respectfully disagrees. The '671 patent discloses a human/murine chimeric IgE designated BAT123 (hu ε, κ) or BAT123 (hu ε1, κ). According to the '671 patent disclosure, this chimeric IgE was constructed using the variable regions of the heavy and light chains of the BAT123 monoclonal antibody. *See*, column 7, lines 21-26 of the '671 patent. The BAT123 monoclonal antibody is a mouse IgG1 antibody. *See*, column 8, lines 40-49 of the '671 patent. The fact that the BAT123 monoclonal antibody is a mouse IgG1, and not a mouse IgE, is confirmed in Liou *et al.* (*J. Immunol.*, 143:3967-3975 (1989)), a scientific publication listing the inventor of the '671 patent as an author. For the Examiner's convenience, a copy of this publication is provided with the accompanying Information Disclosure Statement.

The present claims recite an immunogenic polypeptide that (1) contains a self IgE portion and a non-self IgE portion, and (2) is effective to induce an anti-self IgE response in a mammal. The present claims as amended herein also require the self IgE portion to contain at least a portion of a CH3 domain of IgE. The '671 patent fails to disclose such an immunogenic polypeptide. The '671 patent simply discloses BAT123 (hu ε, κ), a polypeptide with a human IgE portion and a mouse IgG1 portion. Thus, the '671 patent does not anticipate the presently claimed invention. In light of the deficiencies of the '671 patent, Applicant respectfully requests withdrawal of the rejection of claims 1-4 and 11 under 35 U.S.C. §102(b).

The Examiner also rejected claims 1-7 and 11 under 35 U.S.C. §102(b) as being anticipated by EP 0327378. Specifically, the Examiner stated:

> EP 0327378 teaches an immunogenic polypeptide comprising self and non-self domains (portions) of immunoglobulins. The reference further teaches IgE domains, human IgE domains, a self CH3 domain, a polypeptide comprising a nonself-self-nonself construct, and nonself-self-nonself constructs which include nonself CH2 and CH4 domains. (see particularly page 3, fifth paragraph and page 4 last paragraph- page 5 third paragraph). Claim 4 is included in the rejection

because it is an inherent property that the referenced IgE polypeptide is capable of dimerizing.

Applicant respectfully disagrees. Again, the present claims recite an immunogenic polypeptide that (1) contains a self IgE portion and a non-self IgE portion, and (2) is effective to induce an anti-self IgE response in a mammal. The present claims as amended herein also require the self IgE portion to contain at least a portion of a CH3 domain of IgE. At no point does the EP 0327378 reference disclose such an immunogenic polypeptide. For example, the EP 0327378 reference fails to disclose a single immunogenic polypeptide that is effective to induce an anti-self IgE response in a mammal. Thus, the EP 0327378 reference does not anticipate the presently claimed invention. In light of the deficiencies of the EP 0327378 reference, Applicant respectfully requests withdrawal of the rejection of claims 1-7 and 11 under 35 U.S.C. §102(b).

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 8, and 9 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,254,671 or EP 0327378. Specifically, the Examiner stated:

> The '671 patent and EP 0327378 have been discussed supra. The references differ from the claimed invention only in that it does not teach the use of non-placental mammal, specifically, opossum, platypus, koala, kangaroo, wallaby or wombat nonself IgE. However, nonplacental mammals are the most distantly related mammals to placental mammals (such as humans) and would thus be the most obvious choice as a source of the most distantly related nonself IgE.
>
> Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make an immunogenic nonself/self IgE peptide, as taught by the '671 patent or EP 0327378, using non-placental mammal, specifically, opossum, platypus, koala, kangaroo, wallaby or wombat nonself IgE. One of ordinary skill in the art would have been motivated to use said nonself IgE because nonplacental mammals are the most distantly related mammals to placental mammals (such as humans) and would thus be the most obvious choice as a source of the most distantly related nonself IgE.

Applicant respectfully disagrees. As stated above, neither the '671 patent nor the EP 0327378 reference discloses an immunogenic polypeptide as presently recited in claim 1. In addition, neither reference suggests an immunogenic polypeptide as presently claimed. For example, at no point does either cited reference suggest an immunogenic polypeptide that is

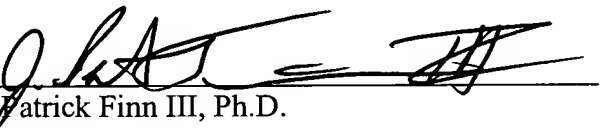
effective to induce an anti-self IgE response in a mammal. Moreover, the cited references, whether applied separately as indicated by the Examiner or in combination, fail to provide a reasonable expectation of success in achieving an immunogenic polypeptide as presently claimed. In fact, the cited references never mention the induction of an anti-self IgE response in a mammal. Thus, neither the '671 patent nor the EP 0327378 reference renders the presently claimed invention obvious. In light of these deficiencies, Applicant respectfully requests withdrawal of the rejection of claims 1, 8, and 9 under 35 U.S.C. §103(a).

CONCLUSION

Applicant respectfully submits that claims 1, 2, and 4-11 are in condition for allowance, which action is requested. Filed herewith is a check in payment of the Petition for Automatic Extension with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: October 12, 2000



J. Patrick Finn III, Ph.D.
Reg. No. 44,109

Fish & Richardson P.C., P.A.
60 South Sixth Street, Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

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